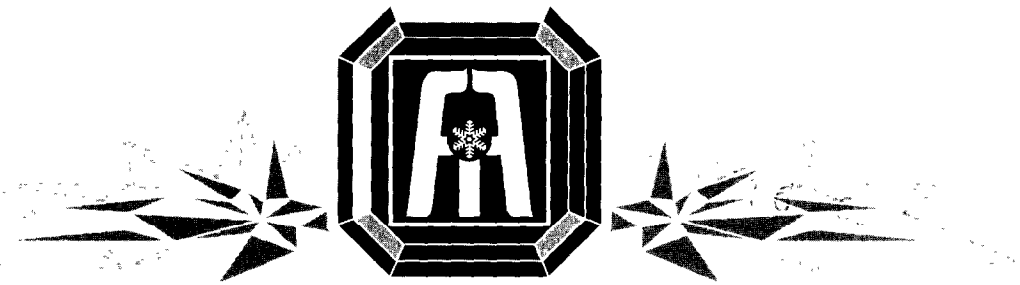

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August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0278 (Prior Notice)

Dear Sir or Madam:

The American Frozen Food Institute (AFFI) is pleased to provide initial comments with regard to FDA's upcoming rulemaking to implement Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. No. 107-188) (the Act or statute). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 550 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

Among other requirements, Section 307 of the Act requires that FDA issue regulations requiring the submission of a notice in advance of any importation of food into the U.S. The notice must identify the article; its manufacturer and shipper; the grower of the article (if known within the specified notice period); the originating country; the country from which it was shipped; and the anticipated port of entry. The Act leaves to FDA the task of specifying the required period of time in advance of importation that the notice must be provided, although it states clearly that the required notice period chosen by FDA may not exceed five days. The Act enumerates several factors the agency may consider in establishing the advance notice period (i.e., its effect on commerce, the locations of the various ports of entry, the various modes of transportation, the types of food imported into the U.S.) but does not foreclose consideration of other factors.

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1. Use of Existing Systems

Like its recommendations with regard to records maintenance, AFFI urges FDA to use existing systems to the greatest extent possible in implementing the Act's prior notice requirements. Doing so will minimize commercial disruptions and save agency time and resources. Linking prior notice with existing information-gathering tools will also help build a "smarter", risk-based system for the selection of food shipments for inspection.

2. Addressing Practical Challenges

AFFI appreciates that implementing the prior notice requirement through existing FDA/Customs information systems will present certain practical challenges. The bulk of the necessary infrastructure is already in place, however, and AFFI believes only minor modifications should be necessary. Specifically, AFFI understands that Customs' Automated Broker Interface (ABI) already permits brokers to enter OASIS data prior to actual importation of a shipment, although that data is not currently transmitted to FDA until entry is actually made.

AFFI urges FDA to modify the ABI/OASIS interface in three critical ways: (1) all OASIS data submitted by brokers in the ABI system prior to importation should be immediately transmitted to FDA; (2) a broker that enters OASIS data prior to importation should receive an immediate acknowledgement of the entry; and (3) the ABI system should assign a unique number to the record created by the broker at the time OASIS data is entered that will remain constant and constitute the entry number for the shipment when importation is finally made.

With these minor changes, AFFI believes the OASIS data entered by a broker (which will be based, of course, on information provided by the importer) can function as the advance notice of importation required by the Act. To perfect this system, the OASIS data screen in ABI should be modified to the extent necessary to allow for entry of the information required by the Act, namely the article being offered for importation (identified on the basis of OASIS product codes); its manufacturer and shipper; the grower of the article; the originating country; the country from which it was shipped; and the anticipated port of entry. The system should not reject an entry if grower information is not entered. The statute makes clear that the required advance notice need not include that information if it is not known at the time notice is made.

3. The OASIS/Advance Notice Entry Should Be a Flexible Document

It is critical that the record created by a broker's OASIS submission to ABI – which will serve as the advance notice required by the Act – remain a flexible document. Put simply, the system should permit brokers to add information to the OASIS entry as it becomes available. To the extent that this "added" information is required for fulfilling the Act's advance notice obligation, it would have to be provided within the minimum required time period, discussed further below.

AFFI believes, however, that other information, that may be unavailable to brokers when the initial OASIS data submission is made, may nevertheless be useful to the agency once it becomes available. For example, brokers may not always have precise information as to the quantity of articles in a shipment well in advance of a shipment's importation. This often occurs because plants estimate production based on maximum capacity. Their initial estimate for importation, therefore, may be high. That estimate is then refined downward over time as production down time is anticipated and accounted for and final numbers for purposes of tariff calculations are prepared. The modified ABI/OASIS system described above should allow brokers to submit updated quantity information after making an initial OASIS entry for the shipment.

AFFI urges FDA to take this opportunity to modify OASIS to allow for submission and consideration of other information that will assist the agency in making better, more risk-based sampling selections. FDA might, for example, utilize Customs' "low risk" importer category. A broker giving prior notice of a shipment by an importer in this category could enter the importer's unique "low risk" importer identification number in the OASIS data screen. Similar modifications to the OASIS screen could be made to ensure that a broker and/or importer participating in the CTPAT program are identified as such to FDA.

4. Minimum-Required Period of Advance Notice

The Act requires that FDA establish the minimum-required period of advance notice of importation. Nothing in the Act suggests, however, that this minimum-required period must be uniform for all types of ports, cargo, and transportation. AFFI strongly believes that the agency may and probably should establish different minimum times based on these factors.

To minimize potential commercial disruptions, it is particularly critical that FDA exercise care in establishing the minimum-required notice period for

border crossing ports of entry. Many food facilities that routinely ship products to the U.S. from Canada and Mexico are located very close to the border. AFFI urges the agency to adopt a minimum-required notice period of two hours for ports such as these.

AFFI notes that, as a practical matter, brokers already make advance entries in the ABI system for the vast majority of border crossing shipments and do so well in advance of two hours before importation. If FDA and Customs modify the ABI/OASIS interface to provide FDA immediate access to OASIS data in ABI, FDA will have more than two hours advance notice of importation for most shipments. For those few it does not, the proposed two-hour time period is still more than sufficient to allow the agency to determine whether sampling/inspection is warranted. Providing for the entry of additional pertinent information into the OASIS system (e.g., CTPAT participation, low risk importer status) would further enhance the meaningfulness of FDA's sampling/inspection selections.

AFFI recognizes that longer minimum notice periods may be appropriate for other types of ports of entry, such as those receiving air and ocean freight. In both cases, however, care should be taken to ensure that the period chosen does not unduly burden the smooth flow of commerce. Based on the information it has received from members, AFFI believes an eight-hour advance notice period would be viable from the point of view of brokers and importers and give FDA a substantial period of time to determine whether sampling/inspection of any particular shipment is warranted.

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AFFI appreciates the opportunity to provide initial thoughts and suggestions with regard to the agency's implementation of the Act's prior notice provisions. AFFI recognizes that the agency's task in this regard is a complex one. It must balance the need to improve the quantity and quality of imported foods inspections with the importance of minimizing disruptions to trade and the overall food supply. AFFI looks forward to working with the agency to achieve an appropriate balance between these two objectives.

Sincerely,

Leslie G. Sarasin

Leslie G. Sarasin, CAE
President and Chief Executive Officer